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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3424-FN]

Medicare and Medicaid Program; Approval of Application from Det Norske Veritas for Continued Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve Det Norske Veritas for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this final notice is effective through September 26, 2026.

FOR FURTHER INFORMATION CONTACT:

Joy Webb, (410) 786-1667.

Lillian Williams, (410) 786-8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations.

Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (CMS) with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS. Det Norske Veritas's **(**DNV's) current term of approval for their hospital accreditation program expires September 26, 2022.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of

the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On April 18, 2022, we published a proposed notice in the **Federal Register** (87 FR 22894), announcing DNV's request for continued approval of its Medicare hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of DNV's Medicare hospital accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An administrative review of DNV's-- (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and (5) survey review and decision-making process for accreditation.

- The comparison of DNV's Medicare hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs).

- A documentation review of DNV's survey process to do the following:

++ Determine the composition of the survey team, surveyor qualifications, and DNV's ability to provide continuing surveyor training.

++ Compare DNV's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospitals.

++ Evaluate DNV's procedures for monitoring accredited hospitals it has found to be out of compliance with DNV's program requirements. (This pertains only to monitoring procedures when DNV identifies non-compliance. If noncompliance is identified by a state survey agency

through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)).

++ Assess DNV's ability to report deficiencies to the surveyed hospital and respond to the hospital's plan of correction in a timely manner.

++ Establish DNV's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of DNV's staff and other resources.

++ Confirm DNV's ability to provide adequate funding for performing required surveys.

++ Confirm DNV's policies with respect to surveys being unannounced.

++ Confirm DNV's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain DNV's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Response to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the April 18, 2022 proposed notice also solicited public comments regarding whether DNV's requirements met or exceeded the Medicare CoPs for hospitals. We received one comment in response to our proposed notice. The comment received expressed support for DNV's hospital accreditation program.

The proposed notice described CMS' process and oversight activities in Section III., Evaluation of Deeming Authority Request, which highlighted the evaluation CMS conducts before granting deeming authority to an AO. In Section V. of this final notice, CMS is highlighting areas, which were identified to have discrepancies or lack of clarity within DNV's standards and survey processes. We note that DNV corrected these discrepancies prior to

renewal of their deeming authority for their CMS-approved hospital accreditation program. CMS continues to strive for increased oversight of AOs.

V. Provisions of the Final Notice

A. Differences Between DNV's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV's hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR part 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of DNV's hospital application, which were conducted as described in Section III. of this final notice, yielded the following areas where, as of the date of this notice, DNV has revised its standards and certification processes in order to meet our requirements at:

- Section 482.13(e)(8)(i)(A) through (C). DNV clarified the specific age-based limits with respect to applicable to the amount of time a patient could spend in restraint and seclusion in hospitals; these limits would supersede any conflicting state law.
- Section 482.15(a)(1). DNV changed its standard to include community-based risk assessment in its requirements and all-hazards definition in interpretive guidelines.
- Section 482.15(b)(7). DNV addressed the requirement that states make arrangements with others hospitals and other providers to receive patients in the event of limitation or cessation of operations, in order to maintain the continuity of services to hospital patients.
- Section 482.23(b)(4). DNV addressed our concerns pertaining to nursing assessment and care plan, to ensure that the requirements are comparable with CMS' requirement.
- Sections 482.24(c)(4)(i)(A) through 482.24(c)(4)(i)(C). DNV revised its standards to fully meet CMS requirements.
- Section 482.28(b)(2). DNV revised its language from a restrictive requirement to include an all patient diet.

- Section 482.41(c). DNV revised language regarding the applicability of National Fire Protection Association (NFPA) to correspond to 2012 NFPA 99, Section 1.3 Application.

- Section 482.52(c)(2). DNV clarified the requirement regarding deferral to state anesthesia practice standards; its prior language was unclear.

- Section 482.53(d) DNV clarified its standard regarding nuclear medicine documentation requirements to include signed and dated language, showing authorship.

- Section 482.57. DNV revised its respiratory care standards to include language reflecting "the needs of the patients" in order to fully reflect CMS' requirement.

- Section 482.58. DNV clarified its standards to include the governing body of the hospital bears the responsibility of assuring medical staff has written policies.

- Section 482.58(b)(1). DNV revised the standard to be more specific and to fully meet the regulatory requirement. DNV's standard had not made it clear that the patients have the right to be informed of total health status in the language they can understand, but rather focused on rules, regulations, and facility responsibilities during facility stay.

B. Term of Approval

Based on our review and observations described in Sections III. and V. of this final notice, we approve DNV as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this final notice is effective September 26, 2022 through September 26, 2026 (4 years). In accordance with § 488.5(e)(2)(i), the term of the approval will not exceed 6 years. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID-19) Public Health Emergency (PHE), CMS was unable to observe a hospital survey completed by DNV surveyors as part of the application review process, which is typically one component of the comparability evaluation. Therefore, we are providing DNV with a shorter period of approval. Based on our discussions with DNV and the information provided in its application, we are confident that DNV will continue to ensure that its deemed hospitals continue

to meet or exceed our required standards. While DNV has taken actions based on the findings noted in section V.A. of this final notice (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements), as authorized under § 488.8, we will continue ongoing review of DNV's hospital surveys. In keeping with CMS's initiative to broadly increase AO oversight, and to ensure that our requested revisions by DNV are completed, CMS expects to perform more frequent review of DNV's activities in the future.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register.**

Trenesha Fultz-Mimms,

Federal Register Liaison,

Center for Medicare & Medicaid Services.

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